REMARKS

With this amendment, claims 23, 25-41, and 43-52 are now pending in the application, and claims 26-41 and 47 have been withdrawn from consideration. The Examiner has rejected claims 23, 25 and 43-46. Claims 48-52 are based on claim 23, but add additional structural limitations to the claims. Claim 48 recites that the virus has the same restriction map as Figure 1, while claims 49 and 50 recite that the virus comprises a protein encoded by specific cDNA sequences. Support for the amendments is as follows:

Claim	Support
48-49, 52	page 1, lines 25-36; page 6, lines 14-21; page 8, lines 21-33; page 20, lines 1-19; and Fig. 1
50	original claim 10; page 11, lines 17-34; page 23, lines 12-30; and page 36, lines 16-35
51	original claim 20; page 12, lines 11-18; page 16, lines 15-20; page 23, lines 12-30; and page 36, lines 16-35

Finally, claim 23 has been amended to correct the inadvertent omission of the prime (') symbol.

FORMAL MATTERS

The Examiner has not considered new claim 47, but has marked it as withdrawn, as it is allegedly directed to an independent or distinct invention. Specifically, the Examiner argues that claim 47 is directed towards a viral variant with different genotypic and phenotypic properties from the virus currently under examination.

Applicants respectfully request that the Examiner consider claim 47. While the Examiner has alleged that claim 47 is drawn to an allegedly independent and distinct invention, he has not shown that it would be a burden to examine the claims together. The law requires that both (1) the inventions are independent and distinct, and (2) there would be a serious burden on the Examiner if restriction was not required. M.P.E.P. § 803. The Examiner has focused on only the first part of this two-part test. In order to properly restrict claim 47 from the remaining claims, the Examiner needs to show that there would be a serious burden in examining the claims together.

Applicants believe that there would not be a serious burden in Examining the groups together and request the rejoinder of this claim.

WRITTEN DESCRIPTION REJECTION

The Examiner has maintained his written description rejection of claims 23, 25, and 43-46. The Examiner believes that the inventors did not have possession of more than one HIV-1 variant (LAV-1_{MAL}) at the time of filing this application. The Examiner argues that the invention as claimed is broadly directed to purified HIV-1 variants that differ genetically in the *gag*, *pol*, and *env* coding regions from three known HIV-1 prototypes (IIIB, BRU, and ARV-2) by the specified amounts (at least 3.4% in Gag, 3.1% in Pol, and 13.0% in Env). Further limitations state that AIDS patient antibodies also bind to the Gag, Pol, or Env polypeptides of the HIV-1 variants and the same polypeptides in HIV-1_{MAL} and that the virus can be detected by stringent hybridization to HIV-1_{MAL} cDNA. The Examiner states that this encompasses a large genus of genotypically/phenotypically unrelated HIV strains.

As previously, the Examiner emphasizes that he believes that the specification only describes the molecular cloning and characterization of a single novel HIV-1 isolate, LAV-1_{MAL}. The Examiner believes that the skilled artisan would not have reasonably concluded that the inventors were in possession of any other HIV-1 variant. The Examiner states that the specification does not provide information on the isolation, characterization, and nucleotide sequence for any other HIV-1 variants.

Applicants maintain that the inventors did have possession of the concept of variant viruses that formed a class with LAV-1_{MAL}. First, the Examiner appears to have discounted the fact that the specification clearly indicates that it includes variants of the LAV-1_{MAL} virus in the invention. It continues by stating that the RNAs of these variants and the related cDNAs hybridize to the corresponding parts of LAV_{MAL}. *See* specification, page 3, lines 4-8. This is an important piece of the written description for the variants.

As Applicants have argued previously, the claimed variants are defined by both structural elements and functional relationships to other known structures. In the present case, the HIV-1 variant virus will bind to AIDS patient sera, when that sera also binds to Gag, Pol, or Env polypeptides of the HIV-1_{MAL} virus deposited at the CNCM. Binding to AIDS patient sera was a well recognized technique for classifying virus antigens. *See* specification, page 16, lines 15-20 (citing *Chang* et al., Expression in Escheria coli of open reading frame gene segments of HTLV-III, Science 228:93-96 (1985)).

Furthermore, the physical structure of the viral genome is described and claimed in the present case. The variants have the following structure: 5'-LTR-*gag-pol-vif-vpr-tat-rev-vpu-env-nef*-LTR-3'. The organization of the viral genome as disclosed and claimed supports the written description of the claimed invention, providing additional structural limitations to the variant viruses.

Claim 23 recites that "HIV-1 variant virus can be detected by stringent hybridization (50% formamide, 5X SSC, at 42°C, for 12-16 hours) with a DNA probe comprising the genomic cDNA of HIV-1_{MAL}." The Examiner argued that this step would not provide any detailed structural information, such as whether the degree of structural relatedness meets the claimed limitations. This limitation, however, in combination with the other limitations does serve to define the variant viruses. It is improper for the Examiner to consider each limitation separately, instead of asking whether the limitations as a whole, and in combination with each other, define the variant viruses sufficiently.

Finally, Applicants have added new claims 48-52, which recite additional structural limitations on the claimed virus. First, these claims specify that the virus is LAV_{MAL}. Second, claims 48-49 recite that the virus has either at least one restriction site from or has the same restriction map as Figure 1, respectively. Claims 50 and 51 recite that the virus comprises a protein encoded by specific cDNA sequences. And, claim 52 further provides that the nucleic acid of the virus hybridizes under stringent conditions to the virus designated HIV-1_{MAL} deposited at the CNCM under No. I-641, or

a restriction fragment thereof, wherein the restriction enzyme is chosen from *Ava*I, *Bam*HI, *Bgl*II, *EcoR*I, *Hinc*II, *Hind*III, *Kpn*I, *Nde*I, *Pst*I, *Sac*I, and *Xba*I.

The specification states that the preferred proteins or glycoproteins of the invention include at least one of the sequences specified in these new claims. *See* specification, page 23, lines 12-30. It continues by stating that "[p]roteins containing of consisting of the 'well conserved stretches' are of particular interest." *Id.*, at lines 31-35. These claims provide yet further structural features of the virus, which are supported by the specification. Therefore, Applicants argue that these claims should be allowed, as well.

Applicants assert that the claimed variant virus is adequately supported by the written description.

II. Prior Art Rejection

The Examiner has again rejected the claims as anticipated by or obvious over *Meyers* (1990), as the Examiner alleges that the claims are not entitled to the benefit of the earlier filed U.S. and French applications. *Myers* was published after the U.S. and French priority dates (U.S. Appln. Ser. No. 07/038,330, filed April 13, 1987, and French Appln. 86401380.0, filed June 23, 1986). Applicants submit that the specification fulfills the written description requirement and, thus, the *Myers* article, published in 1990, cannot be prior art.

III. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: March 22, 2005

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